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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,851	08/29/2003	Richard G. Cartledge	28099-0005	8124

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WASHINGTON, DC 20004

EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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09/18/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com

Office Action Summary

Application No.

10/651,851

Applicant(s)

CARTLEDGE ET AL.

Examiner

Thomas J. Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 23-34 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 23-34 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5 and 23-34 have been considered but are moot in view of the new ground(s) of rejection and the fact that the tool of Ahmadi et al is not coplanar with the ring. The tool of Ahmadi et al lies in an infinite number of planes including at least one parallel plane defined by the ring of Ahmadi et al but none of them are coplanar since the axis of the worm gear is offset from the ring.

Election/Restrictions

Newly submitted claims 43 and 44 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original examined claims (1-5) required a rotating elongated tool to engage the gear. Nothing from the disclosure suggests the combination of the elongated tool with the motors (i.e. circuits) or the combination as part of the elected species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43 and 44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 recites the limitation "before said resuming step" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 34 recites the limitation "before said closing step" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 23-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahmadi et al. Ahmadi et al discloses a method for controlling the internal circumference of an anatomic orifice or lumen, comprising the steps of: introducing an adjustable implant device adjacent to an internal surface near said anatomic orifice or lumen (figs. 7-8), said implant device substantially defining a plane;

securing the adjustable implant device (fig. 1) to tissue adjacent said anatomic orifice or lumen (fig. 7), wherein said adjustable implant device comprises a docking mechanism (51) configured to operably engage an adjustment tool (49) to adjust size or shape of said adjustable implant device; and

adjusting size or shape of said adjustable implant device using an adjustment tool operably engaged with said docking mechanism (fig. 8), wherein said adjustment tool has a proximal portion (at 49) and a distal portion (at 56), and wherein, when operably engaged, at least the distal portion of said adjustment tool is disposed in a non-planar (i.e. no coplanar with

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the plane of the ring, off set from the plane of the ring by at least the thickness of 53) orientation with respect to said plane defined by said implant device.

With regard to claim 4, wherein said step of manipulating said proximal portion of said adjustment tool gear comprises the step of rotating said proximal portion of said adjustment tool gear from a location outside a said closed incision (see fig. 10).

With regard to claim 5, said step of gear manipulating said proximal portion of said adjustment tool from a location outside a said closed incision comprises a step of rotating said proximal portion of said adjustment tool while said distal portion of said adjustment tool is operably engaged with said docking mechanism effective to operate said adjustment mechanism effective to adjust a size or shape of said adjustable implant device (col 5-6, lines 47-23).

With regard to claim 23, said step of adjusting size or shape of the adjustable implant device is conducted under normal or near-normal physiologic conditions (col 5, lines 49-54).

With regard to claim 24, further comprising a step of disengaging said adjustment tool from engagement with said docking mechanism without altering the adjusted size or shape of said adjustable implant device (inherent, the adjustment would not be useful unless maintained while removing the tool).

With regard to claims 25-28, further comprising a step of operably re-engaging said adjustment tool with said docking mechanism (col 6, lines 8-23).

With regard to claims 29 and 31, said step of adjusting size or shape of said adjustable implant device comprises reducing the size of said adjustable implant device (col 5, lines 57-59).

With regard to claims 30 and 23, said step of adjusting size or shape of said adjustable implant device comprises increasing the size of said adjustable implant device (col 5, lines 62-64).

With regard to claim 33, further comprising a step of adjusting size or shape of said adjustable implant device before said resuming step (inherently, there is a pre-adjustment prior to surgery in order to assemble the device).

With regard to claim 34, said further step of adjusting a size or a shape of said adjustable implant device before said closing step is performed. (col 5, lines 47-68)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmadi et al in view of Liddicoat et al (US 6942694). Ahmadi et al discloses a method for controlling the internal circumference of an anatomic orifice or lumen within a body, comprising the steps of: introducing an adjustable implant device adjacent to the internal surface of said anatomic orifice or lumen, said implant device substantially defining a plane;

securing the adjustable implant device to tissue adjacent said anatomic orifice or lumen, wherein said adjustable implant device comprises a docking mechanism configured to operably engage an adjustment tool to adjust size or shape of said adjustable implant device; and

adjusting size or shape of said adjustable implant device using an adjustment tool operably engaged with said docking mechanism. However, Ahmadi et al does not disclose inserting the adjustment tool axially along at least a portion of the anatomic orifice or lumen to operably engage said docking mechanism. It is well known in the art of heart valve surgery to use an approach axially along at least a portion of the heart valve for the purpose of accessing the valve such as taught by Liddicoat et al (figs. 3-4 as an alternative to fig. 8). It is also well known in the art of heart valve surgery and motion transmission to transmit rotary motion at an angle for the purpose of transmitting motion changing direction of rotary motion such as taught also taught by Liddicoat et al (bevel gears 180 and 190 transmit motion at right angles axially along the anatomic orifice). It would have been obvious to one of ordinary skill in the art at the time the invention was made to introduce the tool axially along the heart valve such as taught by Liddicoat et al in order to access the valve and include a means to transmit motion at an angle in order to change direction of motion such as taught by Liddicoat et al on the device of Ahmadi et al. there is a reasonable expectation of success since either the tool or ring could incorporate a motion transmission device such as bevel gears.

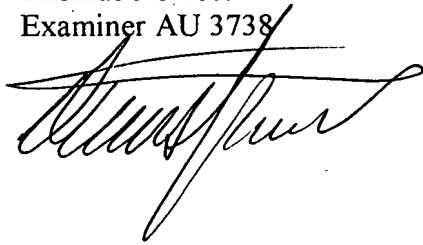
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3738

A handwritten signature in black ink, appearing to read 'Thomas J Sweet', is written over the printed name and title.